January 29, 2002

Color Pigments Manufacturers Association, Inc.
Attn: J. Lawrence Robinson, President
300 North Washington St.
Suite 102
Alexandria, VA 22314

Dear Mr. Robinson:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Acetoacet-*o*-anisidide, posted on the ChemRTK Web Site on August 9, 2001. I commend CPMA for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Chemical RTK HPV Challenge Program website EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the attached Comments on the Chemical RTK web site within the next few days. As noted in the comments, we ask that CPMA advise the Agency, within 60 days of the posting on the Chemical RTK website, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit general questions about the HPV Challenge Program through the Chemical RTK web site comment button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Acetoacet-*o*-anisidide

SUMMARY OF EPA COMMENTS

The sponsor, The Color Pigments Manufacturers Association, Inc. - Diarylide Intermediates Task Force, submitted a Test Plan and Robust Summaries to EPA, dated July 5, 2001, for Acetoacet-*o*-anisidide (CAS # 92-15-9). EPA posted the submission on the RTK HPV Challenge Web site on August 9, 2001.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical and Environmental Fate Data. The Test Plan is adequate for the purposes of the HPV Challenge Program. The submitter needs to provide more input data in its Robust Summary covering Transport between Environmental Compartments (Fugacity) (see Specific Comments on Robust Summaries).

2. Health Effects. Data are adequate for the purposes of the HPV Challenge Program. However, some Robust Summaries need to be enhanced (see Specific Comments on Robust Summaries).

3. Ecotoxicity. EPA considers the aquatic acute toxicity study for fish adequate. EPA also has determined that the calculated algal EC50 endpoint using SAR and a closely related analog is adequate; however, the approach to derive the calculated value is not transparent and needs to be made clearer. The daphnia acute toxicity test is inadequate because the required limit test was not done (see Specific Comments on Robust Summaries).

EPA is requesting that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON THE ACETOACET-*o*-ANISIDIDE CHALLENGE SUBMISSION

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

The submitter's approach to these endpoints is acceptable for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, and transport/distribution).

The submitter's approach to these endpoints is acceptable for the purposes of the HPV Challenge Program.

Biodegradation

The four biodegradation Robust Summaries provide conflicting conclusions, which the submitter did not reconcile. With the first one, a COD test, it is not possible to make an assessment of environmental biodegradation. The fourth one, which uses the Zahn/Wellens method, is a test for inherent biodegradation, and it is not possible to conclude from this type of test whether a chemical is readily biodegradable. However, EPA considers the two remaining Robust Summaries adequate (20-day degradation modified MITI test, and 21-day Biodegradation test).

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate existing data are available for these endpoints. The use of chemical analogs was well supported in the Test Plan based on similar structures, toxicity, and target organs, and appears appropriate; however, some Robust Summaries need to be enhanced (see Specific Comments on Robust Summaries).

On page 6 of the Test Plan, under D. TOXICOLOGICAL DATA, the submitter makes reference to the chemical being an industrial intermediate and therefore, technically, the reproductive toxicity endpoint does not need to be addressed, nevertheless analog data was used to address this endpoint. Other than very general statements in this regard, the submitter would have had to supply much more detailed information to sustain such a claim as outlined in the guidance document for "closed system intermediates."

Ecological Effects (fish, daphnia, and algal toxicity)

The aquatic acute toxicity study for fish and the algal EC50 study are adequate. EPA considers the daphnia acute toxicity test to be invalid because the submitted limit test was not done at $100 mg/L or at the chemical's water solubility limit. Only when a daphnia EC50 can not be reached at > 100 mg/L or at the chemical's water solubility, is there no need to provide an EC50 value.

Specific Comments on Robust Summaries

Environmental Fate

Transport between Environmental Compartments (Fugacity)

The submitter needs to provide half-life input data in its Robust Summary for Transport between Environmental Compartments (Fugacity)

Health Effects

Although the repeated dose and reproductive/developmental studies appear to be well conducted, the Robust Summaries lack the following information: the animals' sex and strain, number of animals used, details of results, such as the time of onset or duration of effects, and statistical analyses. Some of the genetic toxicity study summaries did not include the concentrations tested, characterization of controls, or statistical methods. See EPA's guidance on how to enhance the Robust Summaries to the standard established in EPA's HPV Challenge Program Guidance at the following website: http://www.epa.gov/oppt/chemrtk/robsumgd.htm.

Environmental Effects and Ecotoxicity

Algae

A missing required data element for the SAR-derived algal endpoint is the log Kow value used and its source.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.